



Qualityze

QMS Software Platform

Whitepaper

Key Components of Qualityze Cloud Native EQMS Suite

About Qualityze

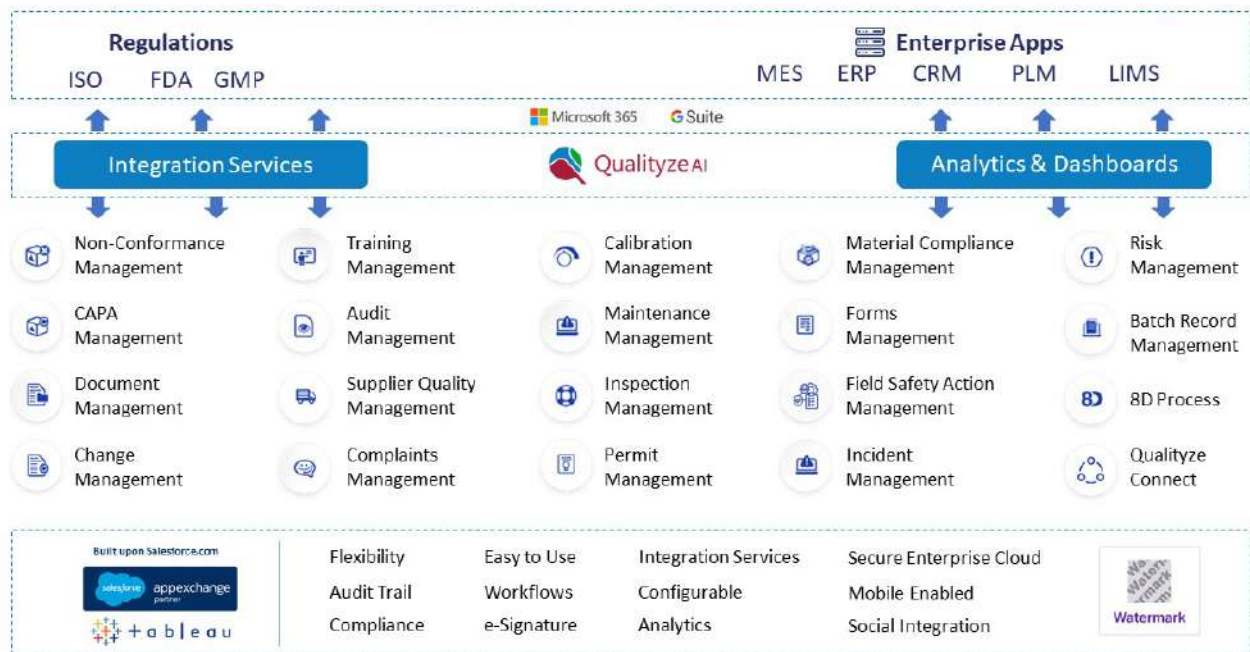
Qualityze has been developing software applications for quality, safety and regulatory teams in manufacturing for more than a decade now. We have solved a variety of problems from helping fledgling startups looking to streamline compliance to manufacturing giants seeking to integrate their quality operations across geographically dispersed locations. Over the years we have built a robust platform with more than 20+ integrated software applications enabling simple to complex automation solutions for quality, safety and compliance teams.

Building an Integrated Quality Management System

Our enterprise suite of products covers diverse manufacturing functions from design & development to product management, quality assurance & quality control, safety management, supplier management, asset management, compliance & regulations management, and post-market analysis. We have worked closely with manufacturing companies of all sizes requiring multiple types of compliances for their products, many of the companies operating in highly regulated industries such as life sciences.

Our products reflect our deep understanding of the complexities of the industries and the competitive environments they have to thrive in. Our platform technology strategy ensures longevity, stability, and scalability. Usability and flexibility are factored-in to enable an integrated user experience. The following solutions empower manufacturing professionals to deliver products with assured quality, safety and compliance.

Qualityze Integrated Ecosystem



Qualityze products integrate seamlessly with other enterprise applications such as MES, ERP, CRM, PLM, LIMS etc. Integration with Microsoft 365 and G Suite make it easy for companies to create documentation in their native environments and move them into Qualityze for further workflow automation. Regulatory standards are incorporated into our solution framework. Teams can easily generate robust reports and dashboards on the go.



QMS Software

Access 20+ integrated software applications for quality, safety, and compliance

Document	Audit	Inspection	Incident
Change	Supplier Quality	Permit	Risk management
Training	Complaints	Material Compliance	Connect [Integration]
Nonconformance	Calibration	Batch mgmt.,	Adverse Events Management
CAPA	Maintenance	Field Safety	8D Process



ISO 9001:2015
Certified Company



Comprehensive Functional Components

Qualityze manages data for multiple functions and automates workflows across business processes including for quality, regulatory and safety. The full life cycle of quality management is automated efficiently reducing manual work to the minimum. All functions are integrated with each other and with other enterprise applications for free flow of quality data. This automation enables teams to deliver products with better quality and also be maintain regulatory compliances accurately. The key features of all modules are outlined in the following sections.

CAPA Management

Features: CAPA Workflow Investigation, Implementation & Effectiveness Review, Creation of Change Request from CAPA Implementation task, Reopen CAPA, Approvals, Void CAPA, Reopen Tasks, Add Tasks

Supplier Quality Management

Features: Supplier Profile, Supplier Selection, Supplier Onboarding, Supplier Change, Notification of Change, Risk Management, Document Management, Supplier Scorecard, SCAR Management, Questionnaires, Supplier Creation, Updating Supplier Details, Questionnaire–Checkout and Check-in

Non-Conformance Management

Features: NC Templates, Supplier Notifications, Address through CAPA, NC Workflow Containment, Disposition, Investigation & Implementation, Investigation Tool- 5 Why, Creation of Change Request from NC, Approvals, Reopen Tasks, Add Tasks

Change Management

Features: Change Templates, Change Request for Document specific changes (New, Revised, Expired documents), Change Request for Product specific changes (New, Update & Revise Products), Change Request creation for Process, Organization or IT Changes, With or without Pre-change Approval and Post Change Approvals, Creation of Change Request from CR Functional task, Reopen CR Tasks

Document Management

Features: Document Types, Collaboration Reviews – Chatter functionality, Approvals, Security – Authorized and View Only entity, Watermark Functionality, Revision History (Version control), Compare Files, Print History, Document Effectiveness or Periodic Review of a Document, Purge Documents, Document Integration with Office365 (Share-Point), Document integration with G-Drive, Document & Change Integration, Extension Documents – Multi language Document Functionality.

Training Management

Features: Document and Instructor led, Document with Read & Signoff, Document with Assessment (Assessment – Single option/Multiple options/Image), Risk Based training, Instructor Led without Assessment (Multiple Session and Attendance), Instructor Led with Assessment, Instructor Led for Document, Training Matrix, Training Program, Document View Profile license to complete Trainings, Job Functions, Non-Licensed users Completing Training through Portal, Risk Based Training, Training Effectiveness – Out Of Office Functionality

CSMS Management

Features: Asset Profiles, Asset Family, CSMS Standard, Schedule Assets for Calibration (Frequency, Estimate & Usage), Schedule Assets for Maintenance (Frequency, Estimate & Usage), Calibration Task, Maintenance Task, Spare Part Inventory

Product Management

Features: Product Profile, BOM Management, Product FMEA, Electronic Batch Record, Inspection Management, Nonconformance Management, Forms Management

Post Market

Features: Customer Complaints, Adverse Event Reporting, Recall & Field Safety Management, Product Registry Management, Product Enquiry

Audit Management

Features: Checklists, Audit Types, Audit Program – Planned Audits, Complete Checklist – Checkout and Check-in (Offline Auditing), Observations & Findings, Observation Closing through Workflow, Observation Closing through CAPA, CR Creation from Response Task, Follow-up Audits and Follow up Observations, Print Compact

Inspection Module

Features: AQL Sampling Plan, Variable & Attributes, Purchase Order, Inspection Type & Standard, 100 % Inspection, Custom Sampling Plan, Inspection Task – Sample based on AQL and Flexible Samples, Bypass Inspection

8D - Investigation Tool

8D stands for 8 Disciplines, and it is a problem-solving approach that involves eight key steps: Defining the Problem (D1), Establishing a Team (D2), Identifying Root Causes (D3), Implementing Containment Actions (D4), Implementing Corrective Actions (D5), Implementing Preventive Actions (D6), Monitoring Progress (D7) and Documenting Solutions (D8)



Permit Management

The Qualityze Permit Management software acts as your virtual assistant, diligently tracking and managing all license types, their intricate details, and associated fees. This automated approach ensures that no license-related detail slips through the cracks. With Qualityze Permit Management you get an intuitive Dashboard. Individual User Profiles simplifies the process of submitting permit-related requests.

Batch Management

Electronic Batch Records, EBR Management software ensures quality by streamlining production batch record management. EBR automation simplifies the setup of master batch record documents, while digital signatures validate data at every stage.

Forms Management

Qualityze Forms Management System not only allows you to digitize your forms, making them accessible, editable, and secure in electronic format. From creation and distribution to data collection, management, and reporting, our system offers an all-encompassing solution for your forms-related needs.

Risk Management

Qualityze Risk Management is a comprehensive solution that enables organizations to effectively manage risks and reduce the cost of quality. By implementing this system, companies can proactively identify, assess, and mitigate risks, leading to improved product quality and substantial cost savings.

Incident Management

Incidents come in various forms, including near-misses, slips, spills, and accidents, and they can be better managed with the right software. Swift notification and collaboration between safety and quality teams are essential. Automating the process not only saves time but also enhances organizational synergy.

Qualityze Central

Centralized Metadata setup. Configure, monitor and optimize system experience. Manage users and the features they can have access to. Create a hierarchy of users based on privileges and permissions such as read only, partial edit or full edit access etc. Manage customizations to the system. Set up workflows. Add rules to control user and system behavior and outcomes. Administer the complete system as per your business rules and process considerations.

Material Compliance

Material compliance involves adhering to the guidelines and restrictions set forth by these regulations such as REACH, RoHS, Conflict Mineral, which aim to minimize the adverse effects of hazardous substances on both people and the planet. This involves thorough documentation, verification, due diligence, and reporting, all of which contribute to a responsible and transparent supply chain ecosystem.

Built-in Quality Frameworks

5Whys, 5Hows, FMEA - quality processes built into the system. Tools used by quality teams are incorporated into the framework.

Common Technical Components

Features: AWS – Attachment Storage Functionality, SharePoint – Attachment Storage Functionality, Electronic Signature, Single SignOn, Electronic Signature with Microsoft Credentials, Electronic Signature with Google Credentials, Electronic Signature with User defined Meaning, GDPR - General Data Protection Regulation, Site & Region based Security, Portals, Reports & Dashboards, Big Objects, Quality Central

Mobile Component

Access QMS on the go. Be updated about quality events and activities on your mobile. Qualityze cloud native EQMS enables you to monitor your quality projects anytime, anywhere. nsiderations.



Integration Components

Move data between manufacturing systems (MES), ERP, CRM, LIMs and QMS. Qualityze is built on the proven and battle-tested Salesforce Cloud Platform.

Usability Components

Features: Quick Search, References, Approvals, Audit Trail & Print, Attachments, Send Email, Chatter, Email Notifications, Multi Language Supported, Multi Browser Supported (Chrome, Safari, Edge), Multi Device Compatibility (Paid & Android Devices), Color Coded Interfaces, Contextual Help

Regulatory Framework and Ecosystem

Qualityze incorporates regulatory standards, and quality tools into the technology framework making it efficient for companies to use it as a go-to platform for quality and compliance. Qualityze is built on the Salesforce Cloud Platform.

Built-in Compliance Tools

- » Digital forms
- » Electronic signatures
- » Watermarks
- » Audit trails
- » Alerts and notifications
- » Personalized dashboards



Technology Platform Advantages

- » Mobile QMS
- » Managed upgrades
- » Validation-ready
- » No code configurability
- » Built-in collaboration tools
- » Automated workflows
- » Ease of integration

Ease of Use

- » Browser based
- » Modular interfaces
- » Visually guided steps
- » Closed loop workflows
- » Contextual help documentation
- » Intuitive navigation
- » Social tools



Integrated Quality Tools

- » 8D
- » 5Why
- » 5How
- » Forms Management
- » Permit Management
- » FMEA

Regulatory Frameworks

- » ISO 9001
- » ISO 13485
- » 21 CFR 820
- » 21 CFR PART 11
- » AS 9100
- » IATF 16949

Platform Security

- » Built on Salesforce Cloud
- » Performance & reliability
- » Stability & scalability
- » Transparent licensing





Reports, Forms and Dashboards Components

All quality activities are captured in reports & converted to visual dashboards for distributing to stakeholders.

Dashboards capabilities

- Get the latest quality dashboards to your email inbox.
- Select frequency when you want to receive the email.
- Subscribe to multiple dashboards.
- Customize charts to better visualize the data.
- Drill down to reports from the dashboards section.
- Download dashboards as images.
- Deliver dashboards to teammates -- set up recipients.

Reports features

- Subscribe to quality reports.
- Attach a report to an email as a formatted XLS file or as a CSV file.
- Add conditions (for summary or full copy) - make sure recipients receive only the most useful information

Artificial Intelligence Components

Artificial intelligence tools enable teams to overcome their human limitations such as crunching large quantities of data in seconds and minutes, detecting patterns from structured and unstructured data, categorizing and classifying information etc.

Quality teams can detect quality defects faster, analyze customer complaints more efficiently, prioritize risks accurately, schedule audits automatically, identify training requirements on time, resolve issues sooner, prevent and predict adverse events based on analyzing trends, generate insights for better forecasting etc. AI tools help increase human productivity significantly and enables businesses to generate innovative solutions efficiently.

What Qualityze QMS AI can do for you.



Collaboration Components and Benefits

Collaboration is critical to successfully meet compliance needs.

Simple automation can help you break the silos:

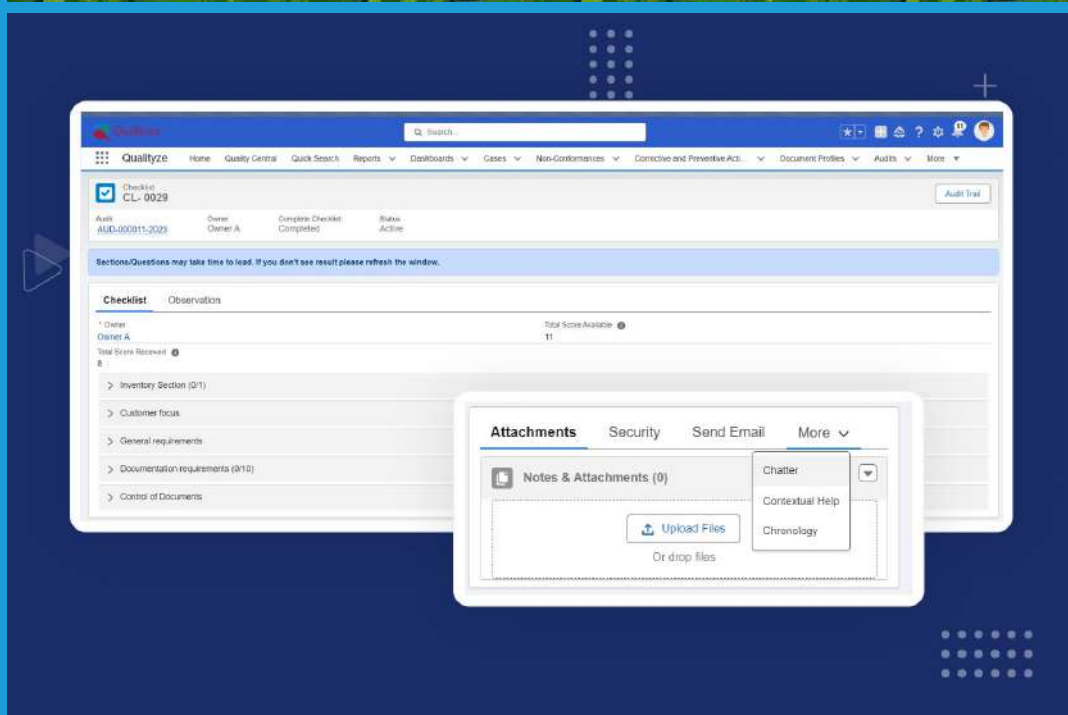
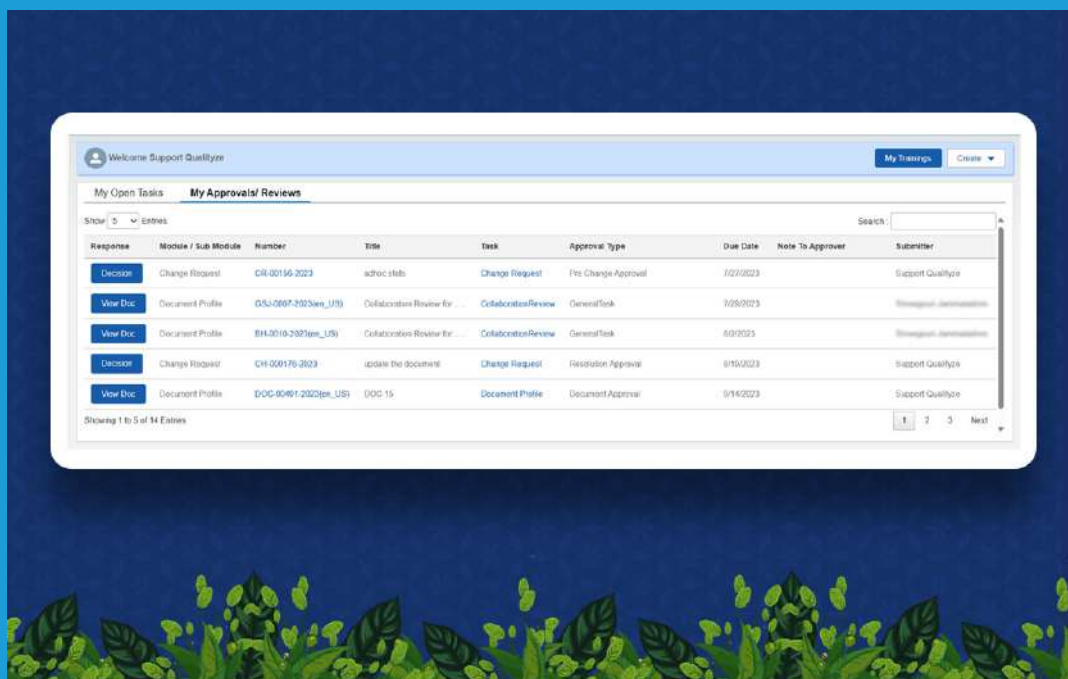
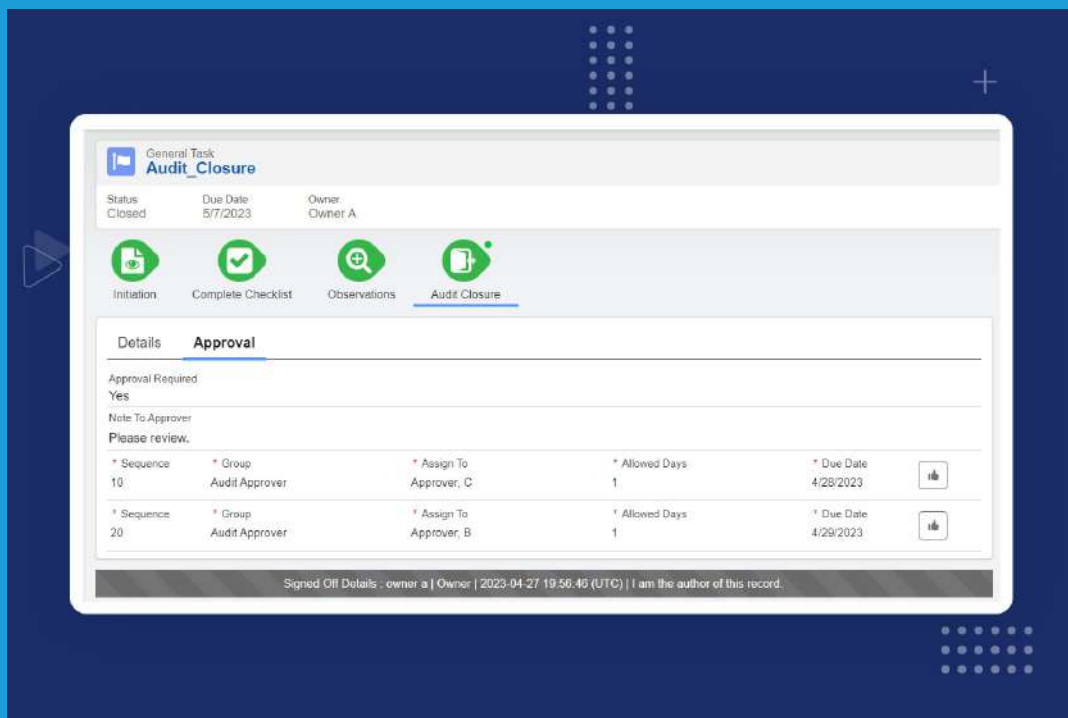
- Getting notified about records that need your attention (via email or chat)
- Alerting approvers automatically of completed records.
- Securing approval through electronic signatures.
- Resolving information through built-in messengers.
- Sending mails directly from within the record.
- Scheduling tasks directly from within the record.
- Conducting polls, gathering feedback.
- Browsing discussion history from within the record.
- Attaching notes and records.
- Analyzing audit trail of records.

Digital Quality Platform Advantages

The foundation of the digital platform provides inherent advantages shared by all the applications built on top of it such as artificial intelligence elements, data security, easy configurability, intelligent search options, task management & audit trails, social communication tools, transparent licensing, mobile enablement, internationalization & localization (support for multiple languages), digital signatures, connectors for integration, compliance tools, analytics components, performance measurement, scalability and reliability tools etc.

Outlining few benefits:

- Easy to set up - import your existing data and get started.
- No software maintenance - always on the latest version.
- Connect to company apps without any IT delays.
- Configure system to your workflow without having to code.
- Access your QMS on mobile. Be informed of quality on the go.
- Browser based application. Access anytime from anywhere.
- Secure cloud technology. Built on trusted Salesforce platform.



Pre-validated EQMS for Life Sciences

Qualityze provides an out-of-the-box preconfigured solution with validation packages - specifically built for life sciences companies. Validation-ready templates include a validation plan, RSD, IQ, PQ scripts, traceability matrix, and validation summary report.

Out-of-the-box Solutions

Many companies rely on our out-of-the-box quality suite to get started and then scale up based on their growth stages. The out-of-the-box offer packages ready-to-implement templates for various quality functions. Designed by domain experts and technical specialists, the solution enables quick implementation based on best practices and based on our team's decades of industry experience in quality and compliance. Instead of waiting for months you can automate your quality processes within weeks. Examples: Document-Change-Training package, NC-CAPA-Audit package etc. You can choose how to bundle your solutions based on our readily available software modules.

Driving innovation in enterprise technology for quality and compliance

Qualityze has been driving innovation in the quality, safety & compliance automation space with 20+ software applications built over a decade and implemented across global locations for multiple industries. We support companies in their modernization journeys and with their digital quality transformation ambitions. We also provide the necessary services and support for expanding their technology footprint and for maintaining a sustainable and automated workflow infrastructure.





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